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Development of a novel polyherbal topical formulation for the management of psoriasis

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Psoriasis is a non-infectious and chronic inflammatory skin disorder, characterized by erythematous plaques with red, itchy patches. We have developed a novel aqueous mixture (SIRB-001) consisting of 3 Traditional Chinese Medicine based herbs; *Rheum palmatum* L. (da huang), *Rehmannia glutinosa* Libosch. (sheng di huang) and *Lonicera Japonica* (jin yin hua) (in the ratio 1:1:3), which has demonstrated promising anti-psoriatic activity mediated by anti-proliferative; pro-apoptotic; anti-inflammatory; anti-angiogenic activities in keratinocytes (HaCaT) and efficacy in TPA and IMQ induced animal inflammation models. SIRB-001 based cream and psoriasis kit (shampoo and lotion) were developed and found to be non-irritant. SIRB-001 cream was evaluated for clinical efficacy in an open-label trial in 21 subjects with psoriasis for 8 weeks (twice daily application). After 14, 28, 42 and 56 days, Psoriasis Area and Severity Index (PASI) scores were reduced by 2.9%, 16.6%, 28.7% and 31.5% respectively ($p < 0.01$). SIRB-001 was well tolerated with no local or systemic side effects. Further, safety and efficacy of SIRB-001 psoriasis kit was assessed in a mono-centric, open label study in 30 subjects with scalp psoriasis treated for 8 weeks. At day-56, there was a significant reduction ($p < 0.001$) in the mean area of total scalp involved, Investigator's Global Severity Scale (IGSS) and Videodermoscopy Scalp Psoriasis Severity Index (VSCAPSI). SIRB-001 psoriasis kit demonstrated a good safety profile with no incidence of local intolerance. Multiplex analysis in serum samples revealed down regulation ($>20\%$) of IL-5, IL-13, GM-CSF, IP-10, MCP-1 and IL-33 after 56 weeks. Hence, SIRB-001 is a highly effective new treatment with a favorable safety profile for management of psoriasis.

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